REMARKS

Applicant respectfully requests reconsideration. Claims 37, 39-45 and 47-56 were previously pending in this application. Claim 37 is amended herein. No claim is canceled. Claims 7, 39-45 and 47-56 are still pending for examination with claims 37, 45 and 54 being independent claims. No new matter has been added.

Rejection under 35 U.S.C. 132(a)

The amendment filed February 25, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure.

Without conceding the correctness of the rejection and solely to advance prosecution, Applicant has amended claim 37 to recite "wherein the immunostimulatory oligonucleotide comprises a phosphate backbone modification and greater than two unmethylated cytosine-guanine dinucleotides, and wherein the oligonucleotide is at least eight nucleotides in length". Support for this amendment is found, for example, in paragraphs 0046-0047 and Table 1. The Office acknowledges and Applicant agrees that the "specification's sequence listing has immunostimulatory oligonucleotides that are at least 8 nucleotides in length and have greater than two unmethylated cytosine-guanine dinucleotides" (See sentence bridging pages 2-3 of the Office Action).

Accordingly, reconsideration and withdrawal of this objection is requested.

Rejection Under 35 U.S.C. 112

Claims 37, 39-44 and 47-53 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office alleges that there are no immunostimulatory oligonucleotides that have all of the claimed limitations and characteristics.

Without conceding the correctness of the rejection and solely to advance prosecution, Applicant has amended claim 37 to recite "wherein the immunostimulatory oligonucleotide comprises a phosphate backbone modification and greater than two unmethylated cytosine-guanine

dinucleotides, and wherein the oligonucleotide is at least eight nucleotides in length". Applicant has shown possession of immunostimulatory oligonucleotides that are least 8 nucleotides in length, have greater than two unmethylated cytosine-guanine (CG) dinucleotides and comprise a phosphate backbone modification by describing distinguishing and identifying characteristics of the composition of the claimed methods and by providing a representative number of species that support these nucleic acids. Applicant respectfully submits that the instantly claimed invention has been described in sufficient detail to allow one skilled in the art to reasonably conclude that Applicant had possession of the claimed invention.

The objectives of the written description requirement are to clearly convey the information that an Applicant has invented the subject matter which is claimed and to put the public in possession of what the Applicant claims as the invention. Possession of the invention may be shown in a variety of ways including description of an actual reduction to practice, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (MPEP § 2163). The application is based, at least in part, on the finding that oligonucleotides containing unmethylated cytosine-guanine (CG) dinucleotides activate lymphocytes as evidenced by *in vitro* and *in vivo* data (See *e.g.*, paragraphs 0046-0047). The evidence presented in the specification demonstrates that the magnitude of this stimulation can be increased if the number of CpG dinucleotides in the nucleic acid are increased (See *e.g.*, paragraph 0046 and Table 1). The specification also teaches that oligonucleotides containing a nuclease resistant phosphorothioate backbone were approximately two hundred times more potent than unmodified oligonucleotides (See *e.g.*, paragraph 0051). The specification describes both structure (an oligonucleotide comprising greater than two unmethylated cytosine-guanine dinucleotides) and structure/function correlation (an oligonucleotide comprising greater than two unmethylated cytosine-guanine dinucleotides induces an improved immune response) (See *e.g.*, Table 1; compare ODN 2 to 2a and 2d and ODN 3D to 3Db). Because the nucleic acids of the genus of the claimed methods have a distinguishing feature, a person of ordinary skill in the art can readily envision, or recognize

members of the claimed genus of immunostimulatory oligonucleotides. Thus, the specification as filed adequately establishes the structure/function correlation that would allow one of ordinary skill in the art to conclude that Applicant had possession of the instantly claimed invention.

Furthermore, in addition to providing a distinguishing feature for the members of the genus of nucleic acids of the claimed methods, the specification also provides a representative number of species to support the genus of nucleic acids of the claimed methods. Namely, the specification provides in Table 1 several examples of nucleic acids that can be used in the claimed methods. The Office acknowledges and Applicant agrees that the "specification's sequence listing has immunostimulatory oligonucleotides that are at least 8 nucleotides in length and have greater than two unmethylated cytosine-guanine dinucleotides" (See page 4 of the Office Action). These representative oligonucleotides which contain greater than two unmethylated cytosine-guanine dinucleotides were shown to induce B cell activation and IgM secretion. Applicant respectfully submits that "[s]atisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed" (MPEP § 2163). By providing both a distinguishing feature for the nucleic acids of the claimed methods and a representative number of species to support these nucleic acids, Applicant has shown possession of the claimed invention.

The Office alleges that paragraph [0046] of the specification does not specifically teach or suggest an immunostimulatory oligonucleotide having greater than two unmethylated cytosine-guanine dinucleotides (See page 4 of the Office Action). Applicant respectfully disagrees. The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement (MPEP § 2163.02). Paragraph 0046 clearly conveys to one of ordinary skill in that art that increased immune stimulation could be achieved by increasing the number of CpG dinucleotides in the nucleic acid. Applicant has demonstrated that immunostimulatory nucleic acids containing greater than two CpG dinucleotides gave increased stimulation.

Applicant respectfully submits that the claims as amended are not anticipated by the art previously cited by the Office, i.e., Hutcherson et al. (5,723,335) as evidenced by Gura et al.

(Science, 1995, 270:575-577). Hutcherson et al does not teach the skilled artisan to prepare and administer to a human a vaccine including a CpG dinucleotide containing oligonucleotide. Hutcherson et al does not teach that the key component of the immunostimulatory oligonucleotide is an unmethylated CpG dinucleotide, and does not disclose any example of a vaccine containing a CpG oligonucleotide to a human. Thus the reference does not provide an adequate teaching to anticipate the claims.

In conclusion, the description of distinguishing and identifying characteristics of the nucleic acids of the claimed methods together with the disclosure of a representative number of species which support these nucleic acids would immediately allow the skilled artisan to envision or recognize the claimed immunostimulatory oligonucleotides. Thus, Applicant has demonstrated possession of the claimed invention and the written description requirement is met.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Double Patenting

Claims 45 and 54-56 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45 and 50 of copending Application No. 11/127,797.

The rejection is a provisional one since claims 45 and 50 in the 11/127,797 application have not been found allowable. If the cited claim is found allowable, Applicants will address the rejection.

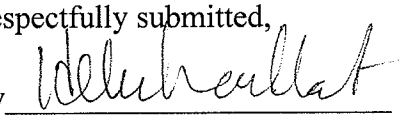
CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1039.70083US05.

Dated: March 15, 2010

Respectfully submitted,

By 

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